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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------|----------------------|---------------------|------------------|
| 10/540,521 | 06/24/2005 | Hirotaka Haro | Q94277 | 5337 |
| 23373 | 7590 | 04/17/2009 | EXAMINER | |
| SUGHRUE MION, PLLC | | | ZAREK, PAUL E | |
| 2100 PENNSYLVANIA AVENUE, N.W. | | | | |
| SUITE 800 | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20037 | | | 1617 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 04/17/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/540,521 | HARO, HIROTAKA |
| | Examiner | Art Unit |
| | Paul Zarek | 1617 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 March 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 5,9 and 10 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 5, 9, and 10 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 24 June 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/16/2009 has been entered.

Status of the Claims

2. Claim 5 has been amended and Claims 9 and 10 have been added by Applicant in correspondence filed on 03/16/2009. Claims 5, 9, and 10 are currently pending. This is the first Office Action on the merits of the claim(s) following a request for continued examination.

RESPONSE TO ARGUMENTS

3. Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over Haro, et al. (Spine, 1997) in view of Haro, et al. (Journal of Spinal Disorders, 1999). Applicant traversed this rejection on the grounds that administration of MMP-7 yielded unexpectedly superior resorption of herniated discs when compared to administration of MMP-3 in an *in vitro* model. Examiner has found Applicant's arguments persuasive and the rejection of Claim 5 over Haro, et al., in view of Haro, et al., is withdrawn in light of the amendment to Claim 5.

4. Amended Claim 5 and newly added Claims 9 and 10 are examined on their merits below.

Claim Rejections - 35 USC § 102

5. The text of Title 35, U.S.C. § 102(b) can be found in a prior Office action.

6. Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Haro, et al. (Journal of Clinical Investigation, 2000, provided in IDS).

7. Amended Claim 5 is drawn to a method of treating a herniated disc or herniated nucleus pulposus (HNP) characterized by directly administering an active ingredient comprising MMP-7 in the absence of exogenous MMP-3 to the affected site of the herniated disc or HNP. Newly added Claim 9 is drawn to a method of treating a herniated disc or HNP consisting essentially of administration of MMP-7 to the affected site of the herniated disc or HNP.

8. Haro, et al., teach that addition of macrophages from MMP-3 null mice to wt intervertebral discs resulted in a $55.2 \pm 2.1\%$ reduction in wet weight of the intervertebral discs (Fig 1; pg 145, col 1, para 3, lines 19-21). It is noted that macrophages from MMP-3 null mice do not produce MMP-3, but are capable of producing MMP-7. Thus, the presence of macrophages from MMP-3 null mice is tantamount to administration of MMP-7 in the absence of MMP-3. Therefore, Haro, et al., anticipates all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

9. The text of Title 35, U.S.C. § 103 can be found in a prior Office action.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haro, et al. (Journal of Clinical Investigation, above).

11. Newly added Claim 10 is drawn to a method of treating a herniated disc or HNP consisting of administration of MMP-7 to the affected site of the herniated disc or HNP.

12. Haro, et al., teach that addition of macrophages from MMP-3 null mice to wt intervertebral discs resulted in a $55.2 \pm 2.1\%$ reduction in wet weight of the intervertebral discs (Fig 1; pg 145, col 1, para 3, lines 19-21). It is noted that macrophages from MMP-3 null mice do not produce MMP-3, but are capable of producing MMP-7. "Consisting of administering MMP-7" is closed language indicating that only MMP-7 (e.g. not cells that produce MMP-7) is administered. Haro, et al., does not teach a method of administering only MMP-7.

13. However, Haro, et al., explicitly teaches the importance of MMP-7 in the process of disc resorption. "Macrophage-derived MMP-7, but not MMP-3, was required for disc resorption and macrophage invasion of disc tissue" (pg 148, col 1, para 2, lines 1-3). Given that the presence of MMP-3 deficient macrophages, which consists essentially of MMP-7, significantly enhances resorption, it would have been *prima facie* obvious to one of ordinary skill in the art to administer MMP-7 to the site of a herniated disc or HNP.

Conclusion

14. Claims 5, 9, and 10 are rejected.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/Rita J. Desai/
Primary Examiner, Art Unit 1625